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Citation

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Reproduction in the Genetic Age: A Proposed Scheme for the Regulation of Assisted Reproductive Technologies

by Laura J. Lindstrom¹

I. INTRODUCTION

A doctor injects the cytoplasm from one woman's egg into the egg of another woman, and a baby is born who expresses the genes of three different people.² A biotechnology company in Massachusetts reports that they have created a cloned human embryo.³ It is now possible for a baby to have (at least) five "parents": the mother and father who raise her, the egg and sperm donors who contribute her genetic material, and the surrogate who carries her to term.

In the last several years, there have been a number of advances in the area of assisted (or advanced) reproductive technology (ART) that are so fantastic that they strain the credulity of even those well-versed in medicine and science. Moreover, the potential medical, legal, psychological, and social repercussions of the applications of these technologies cause most people who hear about their use to worry somewhat about the ramifications. In fact, part of the general fear of these technologies amongst the public is generated by the sense that they are not competent to make decisions, either for their own use of ART or about their opinions on its use by others.

This fear is well-founded. The science used is complicated, and the concerns that result from its use are too far-flung and complex for any one person to be able to anticipate and then address in one cogent, overarching

¹J.D., Harvard Law School, projected 2002; B.A., University of Iowa, 1999.

²Jason Barritt et al, "Mitochondria in Human Offspring Derived from Ooplasmic Transplantation," *Human Reproduction* 16, no. 3 (2001): 513-16, at 513.

³Rachel Benson Gold and Elizabeth Nash, "State Policy in 2001: Major Reproductive Health-Related Developments", *The Guttmacher Report on Public Policy*, vol.4, no.6, p.11, at 14 (Dec. 2001).

policy statement.⁴ These complexities lead to the conclusion that the federal government should become more involved in the regulation of the use of ART. More specifically, the United States Food and Drug Administration (FDA) should take an active role in regulating ART on a federal level.

In Part II.A of the paper, the law and regulation of ART in the United States is detailed. The problems of this vast, piecemeal scheme are highlighted. In Part II.B, the various steps that other nations around the globe have taken with regard to the regulation of ARTs are detailed. This is not only to bring the failings of the United States's model into relief, but also for the purpose of suggesting options that the American regulatory scheme could adopt as its own.

Part III of the paper discusses the policy reasons in favor of giving federal regulatory power over ARTs to the FDA. Both practical and theoretical reasons are discussed, with an emphasis on the history of the role of the FDA in regulating the safety and efficacy of pharmaceuticals and medical devices.

In Part IV, a comprehensive scheme for the federal regulation of ARTs is detailed. This plan would include the formation of a National Commission to conduct broad-based research into the current legal, medical, psychological, and social issues raised by the application of ART and to propose various measures to address them. Under this plan, the FDA would be given the authority to regulate the use of ARTs for safety and efficacy, in line with its current mission to do the same for pharmaceuticals and medical devices. The goal of this plan would be to create a comprehensive national regulatory scheme that would not only protect ART patients, the children born as a result of ART technology, and society at large, but also one that eliminates the confusion in the law and policy in this area so that practitioners and patients are able to make responsible, informed decisions about their use of ARTs.

II. CURRENT REGULATORY SCHEMES

⁴In fact, the potential concerns raised by the application of ARTs are so vast that they cannot be addressed in this paper. Accordingly, the detailed discussion will focus on the regulation of the actual ART procedures, and will touch only briefly on the myriad issues the procedures create within law and society.

A. The American Status Quo

1. Federal

In *Planned Parenthood v. Casey*, the Supreme Court reified the “recognized protection accorded to liberty relating to intimate relationships, the family, and decisions about whether or not to beget or bear a child.”⁵ And currently, the United States has no regulatory body charged with the assessment of genetic and reproductive technologies.⁶ This sweeping constitutional protection of reproductive freedom and the lack of regulation of ART has created a laissez-faire climate in which many different kinds of ART services of varying quality and effectiveness are offered by a wide range of providers.⁷

Clearly, the *Casey* decision states that Americans have the right to make their own decisions about their reproductive lives, including the decision to utilize ART methods. But this does not automatically rule out the possibility that the government might have a role in regulating the safety and efficacy of the use of various ART methods. In fact, the Supreme Court recognized in *Roe v. Wade* that the state has an interest in regulating all medical procedures to “insure the maximum safety for the patient”, including procedures that involve individual reproductive choice (in that case, abortion).⁸ This holding would logically extend to ART methods, which almost always involve intervention with a medical procedure.

Under the Constitution, states are given the power to frame their own health care policy, not the U.S. Congress. As a result, most national legislation in this area is a reaction to state legislation and typically serves two functions: it establishes minimum national standards, or provides federal funding to encourage

⁵505 U.S. 833, 857 (1992).

⁶Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, JOURNAL OF LEGAL MEDICINE 36, 44 (March 2000).

⁷*Id.* at 45.

⁸410 U.S. 113, 150 (1972).

state action.⁹ However, in certain instances, Congress has taken action to legislate national policy with regard to emergency issues raised by ARTs.

a. Minimum National Standards

In 1992, the Fertility Clinic Success Rate and Certification Act was passed by Congress. This was in response to concerns that fertility clinics were misrepresenting their success rates to their potential clients by manipulating the statistics.¹⁰ Under the Act, ART programs must report their rates of success to the Secretary of Health and Human Services, who then publishes a consumer guide annually with the information (the first guide was published in 1997).¹¹ The Act also requires that ART programs identify the laboratories they rely upon to handle and manipulate gametes and embryos. This information is also published in the guide.¹² The Secretary of Health and Human Services was also charged with the task of developing a model inspection and certification program for laboratories that handle embryos and gametes. This program would be implemented by individual states.¹³

The FDA has proposed a new system for regulating products based on human cells and tissue. This new system would define the affected products as being those intended for “implantation, transplantation, infusion, or transfer into a human recipient.” This would, thus, cover the transfer of gametes in ART procedures. The new regulations would require all of these products to be manufactured in compliance with good tissue practice standards. Enforcement and inspection would be a part of the new scheme, and there would be labeling and reporting requirements.¹⁴ However, it is unknown what kind of impact these new regulations

⁹Robert H. Blank, *Regulating Reproduction* 114 (1991).

¹⁰Andrews & Estler, *supra* note 6, at 50.

¹¹*Id.* at 50-51.

¹²*Id.* at 51.

¹³*Id.*

¹⁴Health Canada Online, *Assisted human reproduction: The international scene*, at <http://www.hc-sc.gc.ca/english/media/releases> (last visited Mar. 5, 2002).

would have on the current ART regulatory scheme.

b. Federal Funding Limitations

Federal funding limitations have primarily focused on embryo and fetal research and human cloning research.

A number of prohibitions focus on these issues.

Federal funding for fetal research is permitted under the 1974 National Research Act and regulations promulgated under that law. That law disallows researchers from having any involvement in the decision to abort and the assessment of fetal viability. The law also forbids tailoring the time and method of abortion for the sake of research purposes and payments to women to induce them to have an abortion.¹⁵

Funding for fetal tissue transplantation research is allowed under a 1993 law. This law requires informed consent, forbids provision of tissue in exchange for payment, and forbids the woman aborting to know the person receiving the tissue, among other restrictions.¹⁶

Funding for IVF research is prohibited by a 1995 law that blocks funding for any research in which human embryos are destroyed, discarded, or exposed to serious risk. However, stem cell research is allowed in some cases under a 1993 law.¹⁷ President Bush approved limited federal funding for embryonic stem cell research on August 9, 2001. Federal funds may be used in research on existing stem cell lines only. These existing lines are from embryos created in private fertility clinics that are never going to be used in a treatment cycle and so would be discarded anyway.¹⁸ Funding for stem cells created by cloning, or for the derivation of stem cells from embryos themselves, is prohibited.¹⁹

¹⁵Heather Boonstra, ‘‘Human Embryo and Fetal Research: Medical Support and Political Controversy’’, *The Guttmacher Report on Public Policy*, vol.4, no.1, p.4 (Feb. 2001).

¹⁶*Id.*

¹⁷*Id.*

¹⁸‘‘For the Record: Bush Okays Some Stem Cell Research Funding; Debate Continues’’, *The Guttmacher Report on Public Policy*, vol.4, no.4, p.12 (Aug. 2001).

¹⁹Boonstra, *supra* note 15.

Federal funding is not permitted for human cloning research.²⁰

c. Federal Legislation

In April 2002, President Bush urged the Senate to pass a law banning human cloning for all research and reproductive purposes. This law would make it a federal crime to create a cloned human embryo. The House of Representatives passed this bill in August 2001. The Senate, however, is divided on whether or not there should be exceptions permitted for research purposes.²¹

2. Physician and Scientist Self-Regulation

Standards of practice for physicians are developed from studies and commentary that develop within the medical community. On some occasions, notably in new fields such as ART, professional organizations evaluate this data and recommend standards of clinical practice.²² There are, however, few if any penalties for non-compliance with these self-imposed guidelines.²³ Furthermore, there is no requirement that a physician belong to any peer-monitoring organization.²⁴ Participation is voluntary, and thus any standards promulgated by those organizations are complied with only if a doctor chooses to do so.²⁵ There are also multiple peer organizations in the field of ART, all of which are free to promulgate conflicting recommendations to their membership.²⁶

The American College of Obstetricians and Gynecologists (ACOG) has issued a number of statements of

²⁰Id.

²¹Major Garrett, ‘‘Bush prods Senate to adopt ban on all cloning’’, *CNN.com*, at <http://www.cnn.com/2002/HEALTH/04/10/bush.clon> (April 11, 2002).

²²Jean Macchiaroli Eggen, *The ‘‘Orwellian Nightmare’’ Reconsidered: A Proposed Regulatory Framework for the Advanced Reproductive Technologies*, 25 GA. L. REV. 625, 667–68 (1991).

²³Id. at 668.

²⁴Id. at 669.

²⁵Id.

²⁶Id.

position on the use of ARTs.²⁷ ACOG has broadly approved the use of IVF technology for married couples using their own genetic material and not freezing embryos produced by the procedure. The organization recommends that doctors discuss with their patients how many embryos should be implanted and what to do with those that are not used in an IVF treatment cycle. ACOG also recommends adherence to some minimal technical standards, as set by ACOG and the American Fertility Society. ACOG approves research on embryos outside a woman's body up until the fourteenth day after fertilization, if the research is subject to prior approval by an internal review board (IRB) and is in compliance with "ethical standards".²⁸

The American Fertility Society (AFS) has a broader membership than that of ACOG. It includes medical practitioners, researchers, and other people interested in the field of fertility, whereas ACOG's membership is limited to obstetricians and gynecologists.²⁹ AFS has published minimum standards for the use of IVF and related ARTs by doctors. Their standards include minimum training and qualification for program personnel. AFS has promulgated similar guidelines for gamete intrafallopian transfer (GIFT), including the recommendation that GIFT facilities also provide IVF services.³⁰ AFS has also issued guidelines for artificial insemination procedures, which include donor semen used in ART procedures. These guidelines largely concern the testing of the sperm for HIV and other sexually transmitted diseases (STDs).³¹

AFS also distinguishes between experimental and established procedures in their minimum standards guidelines. As of 1991, IVF, GIFT, the use of donor eggs, the use of donor pre-embryos, and embryo cryopreservation were established procedures. Experimental procedures included egg freezing, ovum transfer, embryo flushing, and egg or embryo micromanipulation techniques. To be in compliance with AFS guidelines, experimental procedures must be done under the guidance of an IRB.³² As time passes and experimental

²⁷*Id.*

²⁸*Eggen, supra* note 22, at 669-70.

²⁹*Id.* at 671, 669.

³⁰*Id.* at 671.

³¹*Id.* at 672.

³²*Id.* at 671-72.

treatments accrue a track record of success, the Board of Directors of AFS moves procedures listed as experimental to the list of established procedures.³³

AFS recommends that all ART programs submit all their success rate statistics to the United States In Vitro Fertilization Registry, or, in the alternative, make those statistics available to their patients. AFS suggests a full disclosure to prospective patients, including the ART clinic's history of experience with a particular treatment and their record of success.³⁴

The American Association of Tissue Banks has established guidelines for obtaining and storing donor sperm. Among their recommendations is the suggestion that donor sperm be screened for medical conditions that would make the donor an unlikely candidate for use in artificial insemination and ART programs.³⁵

The AFS established the Society for Assisted Reproductive Technology (SART). This group was intended to provide quality control that peer-monitoring organizations usually do not. SART members must have proven success rates that meet minimum standards of the organization.³⁶ Because SART membership is voluntary, however, this does nothing to stop clinics which cannot meet the minimum standards from continuing to offer ART services. Only consumer awareness of the SART "seal of quality assurance" gives the minimum standards any effect.

Additionally, where a medical specialty involves quick innovation, as does ART, the self-regulatory system cannot address rapidly enough the new issues that arise from its applications.³⁷ These concerns create a situation in which government regulation becomes necessary to address the problem.

³³*Id.* at 672.

³⁴*Eggen, supra* note 22, at 671. *See supra* Part II.A.1 for a discussion of the federal reporting laws. *See infra* Part II.A.3.b.iv for a discussion of state reporting laws.

³⁵*Id.* at 673.

³⁶*Id.*

³⁷*Id.* at 668.

3. State

a. State Licensing

State licensing is the primary means of regulating the conduct of all physicians, including those who perform ART procedures.³⁸ The statutes which set forth these licensing provisions give the medical profession self-regulation. The profession itself determines who will be permitted to become a physician and assures quality in medical practice within that state.³⁹ The licensing boards are not, however, charged with developing the standards of care and practice for the medical profession.⁴⁰ This responsibility currently rests with peer organizations.⁴¹

b. State Legislation

Under the U.S. Constitution, the state legislatures, rather than Congress, are responsible for health policy.⁴² States do have the power to mandate standards of their own for ART providers, as they do for any health care facility under their licensing power.⁴³

i. Laws Respecting IVF

³⁸*Id.* at 667.

³⁹*Id.*

⁴⁰Eggen, *supra* note 22, at 667-68.

⁴¹See *supra* Part II.A.2 for a discussion of peer monitoring by professional organizations.

⁴²Robert H. Blank, *Regulating Reproduction* 114 (1990).

⁴³Eggen, *supra* note 22, at 674.

A few states have statutes that directly regulate IVF, but often in very different ways. Pennsylvania requires that all IVF practitioners report their data to the state Department of Health, including statistics on discarded and destroyed embryos. There are some minimal fines for willful failure to report correct information.⁴⁴ New Hampshire law directly regulates the doctor-patient relationship in the IVF treatment process. The statutes require that patients receive medical evaluations and counseling about the procedure. Embryos may not remain outside the body for more than fourteen days after fertilization.⁴⁵ Louisiana law requires that IVF clinics conform to ACOG and AFS standards and that their programs be headed by a physician with the training recommended by those peer groups.⁴⁶ Louisiana also broadly regulates extracorporeal embryos created in IVF procedures. They are considered “juridical persons” under this law, and may only be used for implantation in a human woman. They may not be sold or used in procedures where the end is purely research-oriented. The statute also gives the embryo certain rights, defines the ownership of the genetic material, and specifies duties that IVF providers and patients have with regard to the embryo.⁴⁷ Intentional destruction of any fertilized egg is prohibited.⁴⁸

ii. Laws Respecting

Research on Fetuses and Embryos

State statutes that limit experimentation and research on aborted fetuses are fairly common. However, some of these statutes are written in such a way that they do extend to IVF and other ART procedures.⁴⁹ Still other states have passed experimentation statutes that address non-aborted fetuses and embryos. In New

⁴⁴*Id.* at 676.

⁴⁵*Id.*

⁴⁶*Id.* at 673-74.

⁴⁷*Id.* at 676-77.

⁴⁸*Id.* at 677.

⁴⁹*Eggen, supra* note 22, at 674-76.

Mexico, a statute limits research on pregnant women, fetuses, and embryos. The statute doesn't prohibit IVF programs, but limits them by requiring that all embryos produced in an IVF cycle be implanted in the female patient or donated to another woman. Cryopreservation is presumably acceptable under this law (because the purpose is to increase the likelihood that the embryo will eventually be implanted), but prohibits embryo destruction or research that might destroy an embryo.⁵⁰ The Illinois fetal experimentation statute attempted to prohibit sale of or experimentation on embryos and fetuses, unless the experiments were therapeutic to the embryo/fetus itself. This statute expressly included embryos produced during IVF procedures.⁵¹ However, the United States District Court for the Northern District of Illinois found in *Lifchez v. Hartigan* that this law violated the constitutionally guaranteed reproductive rights of individuals.⁵² This case thus calls into question the validity of similar laws in other states.

iii. Laws Respecting Artificial Insemination

Most states have some statutory regulation of artificial insemination by donor (AID). These laws address the situation in which a donor's sperm is used in ARTs, rather than that of a husband (in which case the procedure is called AIH).⁵³ Typically, these laws legitimize the child born as a result of the insemination by designating the inseminated woman's husband as the legal parent, instead of the donor, so long as the husband agreed to the AID procedure. However, some states have laws regulating screening of donors for

⁵⁰*Id.* at 678-79.

⁵¹*Id.* at 679.

⁵²*Id.* at 679-82. See *infra* Part II.A.3.c for the conflicting view of the New York State Task Force on Life and the Law.

⁵³*Id.* at 682-83.

both infectious and genetic diseases.⁵⁴

iv. Laws Respecting ing the Reporting of Success Statistics

A few states have laws respecting the disclosure of success statistics. In Virginia, individual ART clinics must disclose their success rates to their patients. The information given to patients must contain the total number of live births and the percentage of live births per retrieval cycle by age group.⁵⁵

v. Laws Respecting Human Cloning

Six states—Virginia, California, Louisiana, Michigan, Rhode Island, and South Dakota—currently have laws prohibiting the cloning of humans.⁵⁶ The law in Virginia, passed in 2001, bans “the creation of or attempt to create a human being” via cloning.⁵⁷ This type of drafting leaves open the possibility of use of human cloning techniques for the purpose of producing embryos that are destroyed when used for medical and research purposes.

⁵⁴*Id.*

⁵⁵*Andrews & Estler, supra* note 6, at 51. *See supra* Part II.A.1 for a discussion of a similar federal law. In some cases, the 1992 federal law may make moot the state laws regarding success rate reporting. However, some states may require more than the federal law currently provides with regard to disclosure.

⁵⁶*Gold and Nash, supra* note 3, at 11.

⁵⁷*Id. at 14.*

vi. Laws Respecting Surrogacy

After the *Baby M.* case, many state legislatures introduced bills to impact the legal status of surrogate motherhood. By 1990, 73 bills had been introduced in 27 states and the District of Columbia respecting the issue. They were split almost evenly into thirds: one-third proposed to ban surrogacy arrangements, one-third proposed to regulate them, and one-third proposed state commissions to study the issue.⁵⁸

In 1989, Nevada passed a law making surrogacy arrangements legal but subject to strict regulations. Included were required home visits by the state welfare division to all parties involved, proof that the intended mother was infertile, required counseling for the surrogate and the intended parents, and testing for psychological disorders, sexually transmitted diseases, and genetic problems.⁵⁹

Some states, including New Jersey and Louisiana, have made surrogacy contracts unenforceable. In Michigan, a law was passed in 1988 making surrogacy arrangements illegal and punishable by jailing and fines.⁶⁰

Still other states have made surrogacy arrangements legal and enforceable within their borders. Arkansas, one extreme example, passed legislation *endorsing* surrogate motherhood.⁶¹

vii. Review of State Legislation

Problems remain, even with this kind of state legislation. First, these types of laws are not in effect in many

⁵⁸Blank, *supra* NOTE 9, AT 122.

⁵⁹Id.

⁶⁰Id.

⁶¹Id.

states. Second, they address narrow issues in the broad field of ART, most often IVF technology, while leaving most ART-related problems unsolved. And even with the topics that are covered, the setting of standards is sometimes left to a peer organization. And finally, it is currently unclear which kinds of state legislation might run afoul of the constitutional protections of reproductive freedom.

c. State Commissions on Reproductive Policy

This task force, created in 1985 by an executive order of the governor, recommends policy on many issues involving the impact of medical advances on life and death, one of many being ARTs.⁶² The recommendations of the committee include legislation, regulation, and public education measures, as well as others.⁶³

In the fall of 1995, the Task Force began to examine the field of ART in its entirety. The deliberations of the Task Force took two years.⁶⁴ Their research was broad in scope. Every ART program in New York submitted copies of their advertisements, consent forms, and other program materials. Practitioners in selected programs met with the Task Force to provide their input on particular issues in greater detail. They also conducted telephone interviews with people who had used ART methods in New York programs.⁶⁵

The Task Force's conclusions and recommendations were presented in 1998. With regard to the constitutional protection of reproductive choice, the Task Force concluded that these protections were intended to protect coital reproduction by married couples, and that the protections were based on multiple factors. The Task Force concluded that noncoital reproduction by a married

⁶²The New York State Task Force on Life and the Law, *Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy* IX (APRIL 1998).

⁶³*Id.*

⁶⁴*Id.*

⁶⁵*Id.* at *ix-x*. See *supra* Part II.A.3.b for the conflicting view of the U.S. District Court for the Northern District of Illinois.

couple using their own gametes implicated many of those same factors; however, the further that ART moved away from that original model, the factors that originally dictated the protection of reproductive freedom began to disappear. In the end, the Task Force concluded that many courts might believe that the constitutional right to procreate might not apply to procreation using ART methods.⁶⁶

The Task Force made multiple practical recommendations for governing the ART field. These recommendations were lengthy, and included issues of ethical and legal obligations in accepting patients for treatment, in selecting treatments with the potential to result in multiple gestation pregnancies, the introduction of new, untried ART methods, discrimination against patients on the basis of various factors, HIV testing of patients, and psychological and behavioral screening of patients. The recommendations of the Task Force, while calling for some legislation on specific issues such as discrimination and the monitoring of ART outcome data by the state Department of Health, largely relied on physicians and private, professional organizations to self-regulate. While the Task Force did suggest conclusions they felt these actors must necessarily reach as a result of their professional and ethical obligations, the group did not recommend any legislation or regulation to ensure that they did so.⁶⁷

In addition to their broad analysis of the ART field, the Task Force has also made more targeted recommendations on specific problems within the field of ART. In 1987, the Task Force recommended legislation that would make paid surrogacy illegal and render all surrogacy contracts void and unenforceable at law.⁶⁸ Legislation based on these recommendations was enacted in New York in 1992.⁶⁹ As a part of a Task Force study on organ and tissue donation, semen donor

⁶⁶*Id.* at *xii-xiii*.

⁶⁷*Id.* at *xiii-xxii*.

⁶⁸The New York State Task Force on Life and the Law, *Surrogate Parenting: Analysis and Recommendations for Public Policy* (1989).

⁶⁹New York State Task Force, *supra* NOTE 62.

screening came under their scrutiny. The Task Force recommended that the Department of Health be authorized to regulate the collection and distribution of organs and tissues, including donor semen.⁷⁰ In 1990, legislation was enacted pursuant to these recommendations, and since then, the Department of Health in New York has written extensive regulations that directly target all aspects of semen and egg donation.⁷¹

B. The International Response

1. Commissions and Reports

Many countries already have regulation of ART. Many of these nations convened special commissions to consider the problems associated with ART and other new reproductive issues. The following are three countries selected for discussion because their programs are of particular note when considering the possibility of federal regulation of ARTs in the United States.

a. The United Kingdom

The first IVF baby was born in the U.K. in 1978, and that country was the world leader with regard to government policymaking on ARTs. In 1982, the Warnock Committee was created by Parliament to investigate and make recommendations about ARTs. This was the first government-sponsored report on ARTs. In 1984, the Committee issued 64 recommendations concerning the ethical and legal issues ARTs pose

⁷⁰Id.

⁷¹Id.

for society. Notably, these issues were characterized as “emergency” concerns for the British government.⁷² The Warnock report believed that, despite its sympathy for the plight of infertile couples, regulation was needed to oversee the use of ARTs. The Committee recommended a licensing committee be created and that the ARTs of the time, namely AID, IVF, egg donation, embryo donation, and the use of frozen embryos be done only by licensed parties. The report was generally favorable to the use of ARTs, but called for a ban on surrogacy as contrary to the public good.⁷³

Today in the U.K., a government agency, the Human Fertilisation and Embryology Authority (HFEA), began supervising and licensing human embryo research in 1991 after the passage of the Human Fertilisation and Embryology Act (HFEA Act).⁷⁴ It was the first agency of this type in the entire world. The HFEA Act gives HFEA the power to license and monitor clinics that conduct ART procedures of various types. HFEA is also charged with developing a code of practice to guide ART clinics in their operations. The code covers not only the ART procedures themselves, but also the maintenance of a register of gamete donors, records of all treatment cycles, and the outcomes of those cycles. Rules about information and advice given to patients, donors, and clinics are included in the code as well. Also, HFEA reviews information and activities that are covered under the HFEA Act, and provides advice to the Secretary of State on related matters.

Every ART clinic in the United Kingdom must be licensed by HFEA. These clinics are inspected annually by accredited inspectors. HFEA monitors for concerns with regard to the welfare of the child, clinic staff and facilities, donor assessment, information and counseling offered, legal consent, and storage/handling/use of the gametes and embryos.

The HFEA Act was amended in 2000 to allow researchers to use early-stage cloned embryos to create stem cells for research. The Act had previously allowed for embryo research and the creation of embryos for research purposes. However, a part of the legislation required that no cloning for human reproductive

⁷²Blank, *supra* NOTE 9, AT 143.

⁷³*Id.* at 143-45.

⁷⁴Andrews & Estler, *supra* note 6, at 44.

purposes would ever be allowed.⁷⁵

b. Canada

In 1989, the Royal Commission on New Reproductive Technologies was created by the government of Canada.⁷⁶ The Royal Commission's broad mandate allows it the authority to recommend policies that cover any topic in subject area of genetic and reproductive technology.⁷⁷ The Commission has been particularly concerned not only with the views of experts in the fields of medicine, law, and ethics when making its policy decisions, but also the opinions of Canadians at large. In order to ascertain what values and mores Canadians hold that would impact upon the issue, the Commission compiled research from over 70 different fields, including the measurable psychological and social impact of infertility, the use of ART, and genetic research.⁷⁸ The Commission has used more informal, grassroots methods of gathering information as well. They maintain a toll-free telephone number that citizens may call up to report their opinions and experiences in this area.⁷⁹ Canadians, the Commission determined, are particularly concerned with the commodification and objectification of reproduction and genetic material.⁸⁰ They are also anxious that the vulnerable, such as the children who are produced through ART methods and the infertile people who seek these treatments, be protected from the possible negative consequences of potential policy in this area.⁸¹

The Canadian Commission has thus recommended bans on cloning, paid surrogate motherhood, genetic

⁷⁵Health Canada Online, *supra* note 14.

⁷⁶Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies 2-3 (1993).

⁷⁷Andrews & Estler, *supra* note 6, at 44.

⁷⁸*Id.*

⁷⁹*Id.* at 44-45.

⁸⁰*Id.* at 45.

⁸¹*Id.*

enhancement, and sex selection for nonmedical purposes.⁸²

c. Australia

The Australian constitution grants responsibility for legislation over most health-care issues to the several states, which renders the situation in that country remarkably similar to that of the United States.

The medical practice is overseen on the national level by the National Health and Medical Research Council. All medical personnel must work in compliance with the Council's guidelines, and the Council reports to the Federal Health Minister. The Council of the Fertility Society of Australia (FSA) is a multi-disciplinary society formed soon after IVF technology arrived in Australia in 1984. They promulgate guidelines and regulations to govern practitioners in their practice of ARTs.

In 1987, the FSA established the Reproductive Technology Accreditation Committee (RTAC). The membership includes a chairman nominated by the FSA, a reproductive specialist, a scientist, a counselor, a nurse, and a patient representative that are nominated from their respective peer groups. RTAC oversees all IVF in Australia, and they visit and accredit every IVF center on a three year schedule. The Committee has a very strict and detailed set of patient care guidelines. RTAC is funded by IVF clinics through a voluntary process.

The Australian experience with IVF began in the state of Victoria, where the Infertility Treatment Act of 1984 (revised 1995) is in effect. It established the Infertility Treatment Authority (ITA), which has a

⁸²**Id.**

number of responsibilities. The ITA licenses ART clinics that do treatment and/or research and approves practitioners in the field (including doctors, counselors, and scientists). It also enforces the time limit for the storage of sperm, eggs, and embryos in cryopreservation, and maintains three registers on donor-treatment procedures. The ITA monitors decision-making and consent processes and reports information about ART to the legislature and others. The ITA will not issue a license to an IVF clinic unless it is accredited by the RTAC, in order to guarantee that clinics are in compliance with RTAC protocol and the Act's legal provisions.⁸³

III. DRUGS⁸⁴ AND DEVICES VERSUS PROCEDURES: THE LOGICAL NEXT STEP FOR THE FDA

The mission of the FDA includes the charge to ensure that drugs and therapeutic devices for use on humans are safe and effective.⁸⁵ The FDA reviews drugs and medical devices prior to marketing in order to ensure both safety and efficacy, and also monitors after marketing of the drug or device begins to check that the safety and efficacy records remain acceptable. The Administration also inspects manufacturer facilities and tests samples of the products to test for compliance.⁸⁶

This Paper posits that the policy reasons for regulating to ensure the safety and efficacy of drugs and devices apply with equal force to the argument that the FDA should also regulate medical procedures in the same manner. The reasons the FDA's mission has not included the regulation of medical procedures is a purely historic artifact, a result of the manner in which the FDA came into being. Tradition rather than logic

⁸³Health Canada Online, *supra* note 14.

⁸⁴In this Part and throughout the Paper, "drugs" refers to prescription drugs. While some of the statements made about the regulation of drugs in this Paper also apply to over-the-counter drugs, some do not.

⁸⁵Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases and Materials*--2nd ED. 21 (1991).

⁸⁶*Id.*

has been responsible for the distinction between the regulation of drugs and devices and the regulation of procedures.

A. The History of Drug Regulation and the FDA

The reason that the FDA regulates drugs and devices but not medical procedures is not one of logical distinction, but a product of the legislation which led to the creation of the FDA. The Administration grew out of federal legislation that was largely reactionary. The first regulation of pharmaceuticals on a national level that began in 1813 with legislation that was intended to prevent the marketing of fraudulent smallpox vaccinations.⁸⁷ Over time, the concern about the safety and efficacy of all drugs grew. People worried that the drugs they were taking were either adulterated with dangerous ingredients⁸⁸, were being fraudulently marketed when they were in truth ineffective in providing the remedies they promised⁸⁹, or both.

In 1902, the Biologics Act was passed after diphtheria antitoxin infected with tetanus was administered to children in St. Louis, thirteen of whom later died.⁹⁰ The Act required the licensing of drugs in interstate commerce and their purveyors, and required licensed manufacturers of drugs to develop and adhere to procedures intended to ensure safe and pure drug products.⁹¹ The FDA still enforces this law today by regulating biological products such as vaccines, human blood products, and drugs produced through biotechnology.⁹²

Then, in 1906, the Federal Food and Drug Act was passed. This law forbade the sale in interstate commerce

⁸⁷*Id.* at 7 & 378.

⁸⁸*Id.* at 8.

⁸⁹*Id.* at 379.

⁹⁰*Id.* at 8; Philip D. Noguchi, “From Jim to Gene and Beyond: An Odyssey of Biologics Regulation,” 51 *Food and Drug Law Journal* 367, 367-70 (1996).

⁹¹Hutt & Merrill, *supra* NOTE 85, AT 8; NOGUCHI, *supra* NOTE 90, AT 370.

⁹²Hutt & Merrill, *supra* NOTE 85, AT 14.

of drugs that were either adulterated or marketed with fraudulent claims.⁹³ Violations of the Act carried criminal penalties, and the government was empowered to seize the drugs in question.⁹⁴ Standards for purity and quality of certain drugs were set forth in the United States Pharmacopoeia and the National Formulary; manufacturers had to either conform to these standards or label their products otherwise.⁹⁵ Imitation and narcotic drugs were subjected to more stringent labeling requirements with the goal of ensuring safety, efficacy, and truthfulness in advertising.⁹⁶ The FDA was created to handle the administrative burden of regulation, inspection, and enforcement that was created by the 1906 Act.

In 1938, the Food, Drug, and Cosmetics Act (the FD&C Act) was passed to update the 1906 law and address some of the problems the original Act had neglected.⁹⁷ Most notably for the sake of this Paper, medical devices were brought under the oversight of the FDA under the new law.⁹⁸ This was due to growing concerns about the marketing of fraudulent devices.⁹⁹ Other additions to the law included the prohibition against false advertising of drugs and the requirement of informative labeling on drugs, with improved controls to ensure compliance with these laws.¹⁰⁰ Also, the 1938 Act provided that any drug that could be dangerous to health as prescribed would be classified as adulterated.¹⁰¹ One of the reasons behind these other additions to the law was a 1937 incident in which diethylene glycol (antifreeze) was used as an unlisted solvent in a drug preparation. The deadly ingredient was added without any research whatsoever into its safety. At least 73 deaths resulted from the manufacturer's carelessness.¹⁰²

Since 1938, the FD&C Act has been amended multiple times, although the changes have been far smaller in scope than those made in 1938. Generally, the amendments have extended the coverage of the FD&C Act or

⁹³*Id.* at 9.

⁹⁴*Id.*

⁹⁵*Id.*

⁹⁶*Id.* at 9-10.

⁹⁷*Id.* at 11-13.

⁹⁸Hutt & Merrill, *supra* NOTE 85, AT 12.

⁹⁹*Id.*

¹⁰⁰*Id.*

¹⁰¹*Id.*

¹⁰²*Id.* at 476.

enlarged the FDA’s authority over products already under its purview.¹⁰³ The Drug Amendments of 1962 overhauled the method by which the FDA regulates new drugs¹⁰⁴, and the Medical Device Amendments of 1976 changed the manner and scope of FDA regulation of devices.¹⁰⁵ In 1990, the Safe Medical Devices Act altered somewhat the 1976 regulatory structure with regard to devices.¹⁰⁶

B. How Drugs and Devices Are Currently Regulated

1. Drugs

a. FDA Approval of New Drugs

The 1962 Drug Amendments created a system of premarket approval of every new drug, with the focus of the inquiry being safety and efficacy.¹⁰⁷ A “new drug” is one that is not generally recognized as being safe as it is proposed to be dosed, or alternatively, a drug generally considered safe but which has not been used extensively enough for a long enough period of time for there to be adequate certainty of that fact.¹⁰⁸ Before a new drug can be marketed, a “new drug application” (NDA) must be approved by the FDA.¹⁰⁹ In order to be approved, the new drug must be shown by “substantial evidence” to be effective and safe.¹¹⁰

The application process is both lengthy and costly. First, a manufacturer does research that identifies drugs which seem likely to be beneficial to humans. This takes, on average, between 1-4 years.¹¹¹ Next, before submitting an NDA, the manufacturer must either have conducted testing on both animals and

¹⁰³*Id.* at 13.

¹⁰⁴See *infra* Part III.B.1 for a discussion of the current FDA regulatory scheme for drugs.

¹⁰⁵Hutt & Merrill, *supra* NOTE 85, AT 13-14. See *infra* PART III.B.2 FOR A DISCUSSION OF THE CURRENT FDA REGULATORY SCHEME FOR DEVICES.

¹⁰⁶*Id.* at 746 n. 2.

¹⁰⁷*Id.* at 13 & 475.

¹⁰⁸*Id.* at 476.

¹⁰⁹*Id.* at 478.

¹¹⁰*Id.*

¹¹¹Hutt & Merrill, *supra* NOTE 85, AT 514.

humans intended to demonstrate safety and efficacy, or must have plans to do so.¹¹² This research must also identify the side effects of the new drug, and may take between 4-6 years.¹¹³ The research and corporate decisionmaking about research and development are typically not regulated directly by the FDA. However, the types of research that the FDA requires before it will approve an NDA indirectly guides drug companies in the kinds of research it undertakes with a new drug.¹¹⁴

Any study of a new, unapproved drug in human subjects must first file a claim for an exemption for an “investigational new drug” (IND) with the FDA. If the FDA does not respond within thirty days, the drug company may begin human trials.¹¹⁵ When deciding whether or not to reject the claim of exemption, the FDA is primarily concerned with protecting the research subjects, and secondarily interested in ensuring appropriate scientific design of the studies.¹¹⁶ Human research is conducted in three phases, with the scope of the research becoming broader as it progresses.¹¹⁷ Only one in ten drugs investigated at the IND stage will be found worthy of an NDA filing.¹¹⁸

Finally, the FDA will evaluate and (hopefully) approve the NDA. An NDA must contain all information, both positive and negative, that has been found during the research into the drug’s safety and efficacy, and must disclose the manufacturing and quality assurance procedures.¹¹⁹ The FDA is required not to approve an NDA unless the evidence provided demonstrates safety by all reasonable research methods.¹²⁰ How the FDA assesses safety has never been disclosed in regulations, but a former FDA Commissioner once stated that there were three criteria considered: the potential benefits conferred by the drug, the risk associated

¹¹²*Id.* at 513.

¹¹³*Id.* at 514.

¹¹⁴*Id.*

¹¹⁵*Id.* at 515.

¹¹⁶*Id.* Approval of the IRBs at the institution where the research is being conducted may also be required. *Id.*

¹¹⁷Hutt & Merrill, *supra* NOTE 85, AT 515-16.

¹¹⁸*Id.* at 516.

¹¹⁹*Id.* at 519.

¹²⁰*Id.* at 522.

with the drug's use, and the relative weight of those benefits and risks.¹²¹ The FDA is also required to withhold approval of an NDA unless adequate scientific evidence demonstrates that the drug will be as effective as the manufacturer claims when used as recommended.¹²²

The process of FDA review takes between 2-3 years.¹²³ Studies have shown that the entire process, from research to FDA approval, takes between 7 and 13 years and costs between \$30-\$50 million dollars.¹²⁴ Some NDAs receive expedited reviews if the drug in question is considered to one that will be a substantial and important medical advance or if it is for the treatment of a potentially fatal or extremely severe illness.¹²⁵ The FDA is not required to explain an approval of an NDA, although it has been FDA policy to do so.¹²⁶ If the FDA decides to refuse approval of an NDA, the developer may request a hearing on the issue of the drug's approvability.¹²⁷ It is rare that either approvals or denials of an NDA are challenged.¹²⁸

After an NDA is approved, the sponsor must continue keep records and report to the FDA on the performance of the drug. FDA regulations require that the manufacturer periodically submit information on safety and effectiveness of the drug, and also requires prompt notification of any serious adverse reactions to the drug.¹²⁹ Since 1962, some approvals of drugs have been revoked in the occasional instances in which the drugs caused severe adverse reactions in some users that were only discoverable when the drugs were used in a very large group of patients.¹³⁰

b. Labeling Requirements

Under the FD&C Act, there are requirements and restrictions for the labeling of prescription drugs. Any

¹²¹*Id.*

¹²²*Id.* at 525.

¹²³Hutt & Merrill, *supra* NOTE 85, AT 514.

¹²⁴*Id.* at 514 & 559.

¹²⁵*Id.* at 529-31.

¹²⁶*Id.* at 531-32.

¹²⁷*Id.* at 520.

¹²⁸*Id.* at 532.

¹²⁹Hutt & Merrill, *supra* NOTE 85, AT 537.

¹³⁰*Id.* at 544.

drug with anything false or misleading on its label is “misbranded” and is thus a violation of the law.¹³¹ Furthermore, the label must contain adequate directions for use and adequate warnings against unsafe uses of the drug.¹³² The warnings given and the claims made by a manufacturer about a new drug are submitted to and approved by the FDA during the NDA process.¹³³ The FDA may require a manufacturer to change, include, or remove claims and warnings, or face denial of its NDA.¹³⁴ The label must also include the name and address of the manufacturer.¹³⁵

The FDA also regulates claims made about drugs in advertising after marketing begins.¹³⁶ Ads for drugs must be truthful, fairly balanced, and not misleading about side effects, contraindications, drug comparisons, safety, effectiveness, testimonial endorsements, approved or recommended uses, and the scope, relevance, results, accuracy, and/or recency of knowledge and research about the product (among others).¹³⁷ The FDA does allow advertisement of a drug’s price, with certain restrictions.¹³⁸

c. Limits on Physician Ability to Prescribe

Physicians occasionally wish to prescribe an FDA-approved drug for a use which is not approved. Often, there is some (perhaps even compelling) evidence that a particular drug has therapeutic value in treating a condition; however, at the time of FDA review and approval of the NDA, there was not sufficient evidence that the drug was safe and effective for that purpose.¹³⁹ While the FDA does not permit a drug manufacturer to promote the drug for the unapproved use, it does not consider a physician prescription of a drug for an

¹³¹*Id.* at 388.

¹³²*Id.* at 422.

¹³³*Id.* at 396 n. 6 & 422.

¹³⁴*Id.*

¹³⁵Hutt & Merrill, *supra* NOTE 85, AT 451.

¹³⁶*Id.* at 454.

¹³⁷*Id.* at 454-58.

¹³⁸*Id.* at 465.

¹³⁹See *id.* at 617. *It is possible for a manufacturer to conduct further research and submit a supplemental NDA to the FDA in order to receive approval for a new use of an already-approved drug. Id.*

unapproved use to be a violation of the FD&C Act.¹⁴⁰

2. *Devices*

The Medical Device Amendments of 1976 created a new scheme for regulating medical devices from their development through their marketing.¹⁴¹ These Amendments created a system of classification for all medical devices that corresponded with the FDA’s level of certainty about a particular device’s safety and effectiveness. All devices are subject to certain “general regulatory controls”, regardless of classification.¹⁴²

Class I devices require no premarket approval; regulatory controls are believed to be sufficient to guarantee the safety and efficacy of these devices.¹⁴³ These devices typically pose very few health risks for the user. Approximately 30 percent of all devices are rated Class I.¹⁴⁴

For Class II devices, regulatory controls are not considered sufficient to guarantee safety and efficacy. Thus, FDA requires the development of a “performance standard” for the device, based upon data available. Class II devices must comply with the FDA-established performance standard.¹⁴⁵ Approximately 60 percent of all devices are Class II.¹⁴⁶

Class III devices are those for which regulatory controls are not enough to guarantee safety and efficacy and insufficient data exists to determine a performance standard. Premarket approval is required for these devices.¹⁴⁷ Approximately 10 percent of all devices are in Class III.¹⁴⁸

Notably, FDA has factored public opinion into its decisions with regard to the classification of certain controversial devices. For example, FDA originally planned to classify electroconvulsive therapy devices (used to

¹⁴⁰*Id.* at 617.

¹⁴¹Hutt & Merrill, *supra* NOTE 65, AT 745.

¹⁴²*Id.* at 746.

¹⁴³*Id.* at 745.

¹⁴⁴*Id.* at 750.

¹⁴⁵*Id.* at 745.

¹⁴⁶*Id.* at 750.

¹⁴⁷Hutt & Merrill, *supra* NOTE 85, AT 745.

¹⁴⁸*Id.* at 750.

administer “shock treatments” to psychiatric patients) in Class II. However, when the public raised concerns about the propriety of the use of this kind of treatment, the FDA decided to give the devices a Class III rating.¹⁴⁹

There are some devices for which there have been special rules created. For example, uses of cardiac pacemakers must be registered. Devices must comply with these rules, in addition to the rules that apply to their particular level of classification.¹⁵⁰

A device may thus only be marketed if it satisfies one of three requirements: one, the manufacturer submits a premarket notification (PMN) to the FDA that shows the device is “substantially equivalent” to a device that was in use prior to the passage of the 1976 Amendments; two, it was subject to premarket approval (PMA) by the FDA; or three, it was reclassified on petition to the FDA from Class III to Class II or I.¹⁵¹

a. Class III: Premarket Approval

Class III devices which are largely new innovations in medicine must pass a premarket approval by the FDA.¹⁵² This requires the compilation of data on safety and effectiveness of the device. In order to obtain this data, the FDA allows the use of investigational new devices in clinical trials.¹⁵³ If the use of the device is considered to be a significant risk to patients, the FDA requires an approval process analogous to the one used for new drugs.¹⁵⁴ Devices that are not considered significant risks may merely obtain IRB approval before clinical trials begin.¹⁵⁵ Experimental devices may be used in emergency situations without prior approval if it is the only possibility for saving the life of a patient who will die without immediate care.¹⁵⁶

¹⁴⁹*Id.* at 751.

¹⁵⁰*Id.* at 746.

¹⁵¹*Id.* at 745.

¹⁵²*Id.* at 756.

¹⁵³Hutt & Merrill, *supra* NOTE 85, AT 756.

¹⁵⁴*Id.*

¹⁵⁵*Id.*

¹⁵⁶*Id.* at 759-60.

Once a manufacturer has gathered data on safety and effectiveness, it applies to the FDA for approval of the Class III device. The application is reviewed by an advisory committee, which gives an opinion on whether the scientific evidence merits approval of the device.¹⁵⁷ When deciding whether to approve a new device, FDA weighs the probable health benefits against the probable health risks in the use of the device. If the benefits outweigh the risks, the device is considered safe and effective.¹⁵⁸ After approval, the FDA may occasionally require postmarketing studies of some kind.¹⁵⁹

There is an alternative track for approval of a device. This is the product development protocol (PDP). Under a PDP, the FDA and the device manufacturer develop a testing program together, and agree that if the program is successful, the FDA will approve the device for marketing.¹⁶⁰ However, this alternative has only been used rarely.¹⁶¹

b. Class II: Performance Standards

Performance standards are set either by the FDA or voluntarily created by device manufacturers and are intended to gauge the performance of devices which pose a moderate risk to the patients who use them.¹⁶² Compliance with these standards assures a minimum level of safety and effectiveness without the greater administrative burden of acquiring premarket approval.¹⁶³

When creating the standards, the FDA considers the device's uses and the potential health risks and benefits posed by those uses.¹⁶⁴ Riskier Class II devices require mandatory performance standards. Manufacturers of devices posing moderate risk may only be required to develop their own voluntary performance standards.¹⁶⁵

¹⁵⁷*Id.* at 762.

¹⁵⁸*Id.* at 766 n.1.

¹⁵⁹Hutt & Merrill, *supra* NOTE 85, AT 767 N.7.

¹⁶⁰*Id.* at 768.

¹⁶¹*Id.* at 769.

¹⁶²*Id.* at 772-73.

¹⁶³*Id.* at 773.

¹⁶⁴*Id.* at 775.

¹⁶⁵Hutt & Merrill, *supra* NOTE 85, AT 774-75.

Some Class II devices are considered sufficiently low-risk that they are subject only to special controls. These controls may include postmarket observation, patient registries, guidelines, recommendations, and others.¹⁶⁶

c. All Devices: General Regulatory Controls

These controls apply to medical devices of all types. Certain provisions require clear, truthful labeling and prohibit adulteration and misbranding.¹⁶⁷ The FDA has also set good manufacturing practice regulations for devices, based on the risks to health from the use and possible failure of a particular device.¹⁶⁸ There are notification, repair, refund, and replacement requirements that apply to medical devices that pose an unreasonable risk of substantial harm to the user.¹⁶⁹ The FDA may ban certain devices, primarily with the goal of quashing “quack” devices.¹⁷⁰ The FDA requires that some devices be available only by prescription.¹⁷¹ And finally, the FDA may require that a device manufacturer keep records about the devices and submit that information in reports to the FDA.¹⁷²

3. Advantages and Disadvantages of the Drug and Device Regulatory Systems

The requirements for premarket review and approval of drugs and devices, leads the FDA to be significantly involved in the decisionmaking of the private manufacturers of new drugs, and the result of this extensive and intrusive regulation is that the time and money invested in bringing a new drug to market is significantly

¹⁶⁶Id. at 777.

¹⁶⁷Id. at 746, 778-85.

¹⁶⁸Id. at 785-86.

¹⁶⁹Id. at 788-89.

¹⁷⁰Id. at 788.

¹⁷¹Hutt & Merrill, *supra* NOTE 85, AT 786-87.

¹⁷²Id. at 787-88.

increased.¹⁷³ This has troubling consequences.

First, it slows the rate at which new drugs and devices are developed and brought into therapeutic use. This is particularly important not just because of the impact on the biomedical subsector of the economy. People in the United States who are suffering from diseases and disorders for which adequate treatments are not currently available are personally injured if the regulations discourage drug and device manufacturers from pursuing the innovations they would have made if not hindered by the overwhelming cost of the very regulations that were instituted to protect the public. Even drugs and devices that manufacturers do choose to develop are not made available to the public for many years, until they can pass FDA's scrutiny. Tragically, some of the most serious diseases are those for which there are currently no effective treatments whatsoever—for example, Lou Gehrig's, Huntington's, and Alzheimer's diseases. If the regulatory apparatus has slowed even somewhat the development and availability of treatments or cures for medical problems which cause death and/or great suffering, it would be a strong argument against the current heavy regulation of drugs and devices.

However, measures can and have been taken to lessen the negative impact of the regulation of drugs and devices on innovation. Where critically ill patients will suffer serious health problems or death if they wait for a drug or device to be approved for use in treatment, there are opportunities for them to gain access to experimental treatments. For example, there are emergency use provisions for devices, which allow doctors to use an unapproved device to treat a patient who would otherwise die.¹⁷⁴

Laws have also been passed to lessen the financial burden on innovation in drugs and devices. For example,

¹⁷³*Id.* at 475.

¹⁷⁴*Id.* at 759-60. *See supra* note 156.

the Orphan Drug Act of 1983 provides incentives for manufacturers to invest in the development of drugs to treat rare diseases (defined as a condition affecting fewer than 200,000 Americans), for projected sales of such drugs are typically so low that manufacturers would not otherwise invest in the research, development, and administrative processes required to bring them to market.¹⁷⁵ These include tax and marketing incentives.¹⁷⁶ The FD&C Act further requires the FDA to encourage orphan drug sponsors to allow people suffering from the disease the drug is intended to treat access to the drug during clinical trials.¹⁷⁷ These laws combat the reduced incentive for innovation on the part of drug and device manufacturers in the face of the regulatory burdens imposed by legislation.

Another concern raised by opponents of regulation is that the FDA regulatory scheme limits consumer freedom of choice in their medical treatment. The FDA's goal is to ensure that drugs and devices are safe, effective, and marketed in a truthful manner. Some consumers, however, would argue that they require only accurate information about a product, and not premarket approval. Given adequate data, some consumers would prefer to make their own decisions as to whether a drug or device is one they would like to make use of in their medical treatment. The most compelling version of this argument is found in the cases of patients who are terminally ill, in extreme pain or discomfort, or who have had their activity narrowly limited by a condition. These people may arguably have much to gain and little to lose from gaining access to treatments which have not been subject to FDA review and approval.

There are answers to this concern as well. First, as stated above, seriously or terminally ill patients may have access to drugs that have not yet completed the FDA's NDA approval process. This lessens the burden of regulation on people with critical health problems. However, it is true that some freedom of choice remains

¹⁷⁵*Id.* at 566.

¹⁷⁶*Id.*

¹⁷⁷Hutt & Merrill, *supra* NOTE 85, AT 518 N.8.

restricted by the regulations. Yet, the trade-off made in the area of freedom of choice is justified by the overwhelming benefits of regulation. Very real, serious dangers are posed to the public at large by the unregulated manufacture and sale of drugs and devices. The result of deregulation would be the potentially widespread use of drugs and devices, intended to be therapeutic, which would in fact pose harms to health. These harms might be the result of intentional recklessness and/or fraud on the part of manufacturers. More often, perhaps, risks would arise because, due to economic pressures, manufacturers would not invest nearly as much time or effort in determining the safety and effectiveness of a drug or device before bringing it to market.

It is also important to note that “freedom of choice” would be an illusion for many patients in a world without regulation of drugs and devices. The quality of drugs and devices would likely be closely correlated with their cost. Many Americans would likely be unable to afford high-quality treatments under such a regime. Insurance companies might refuse to foot the bill for a safer device where a less expensive but slightly riskier alternative is on the market. And children, who have no voice whatsoever in determining their own medical care, would find the quality of their health care at the mercy of their parents’s budget constraints.

It is also important to note that “freedom of choice” can exist only in a regime that retains some type of labeling or disclosure requirement for drugs and devices. Without the information about safety, efficacy, side effects, and intended uses that is gathered during the regulatory process and then disclosed to patients, consumers would not have access to the information necessary to make informed decisions about their medical care. And it is likely that, even if labeling and disclosure requirements were retained, manufacturers of drugs and devices would not do nearly as much research on their products as they do under the requirements of the current regulatory scheme, thus reducing the ability of any consumer to know what exactly their treatment options entailed.

C. The Analogy Between Drugs, Devices, and Procedures

The very same policy arguments which tip the balance in favor of federal regulation of drugs and devices also martial in favor of FDA regulation of medical procedures. Many would undoubtedly argue that doctors are the ones who perform procedures, and that they are capable of regulating themselves as to whether or not a procedure is safe, effective, and indicated in a particular situation. However, it is also possible to make the identical argument about therapeutic drugs and devices. This parallel begs the question—why, then, are drugs and devices regulated by the FDA while procedures are not? Are there logical reasons for the difference?

In fact, it appears that the dichotomy is explained largely by the vagaries of legislative and administrative history. As discussed above, the laws which culminated in the creation of the FDA were passed in response to national crises over the safety and efficacy of drugs on the market (usually vaccinations).¹⁷⁸ Fraud was common, and lawmakers undoubtedly reasoned that where fraud could cause serious harms to health, consumer protection and government regulation were warranted.¹⁷⁹ Later, the same concerns developed with regard to medical devices, and when the food and drug laws were revamped in 1938, devices were included as subject to regulation.¹⁸⁰

No crisis of similar proportions has ever come to such prominence as to cause the U.S. Congress to enact similar legislation with regard to medical procedures. However, this should not be interpreted to mean that one has not occurred, or that there is no potential for one to occur. In fact, consumer fraud with regard to medical procedures would be much easier to perpetrate without detection, for a host of reasons. First, procedures are not often marketed in the manner that drugs and devices often are. It is rare to see a television advertisement touting the wonderful benefits of a medical procedure. Drugs and devices are

¹⁷⁸See *supra* Part III.A.

¹⁷⁹*Id.*

¹⁸⁰See *supra* Part III.B.

frequently marketed directly to consumers through print and broadcast media; ads for contact lenses, allergy medications, hearing aids, birth control pills, motorized wheelchairs, and antidepressants, among others, are seen daily by most American consumers. The medical procedures which are marketed directly to consumers, such as corrective laser eye surgery and breast augmentation, typically have similar features: they tend to be elective, cosmetic, and/or prominently feature the use of a regulated medical device.¹⁸¹

The vast majority of medical procedures, however, are unglamorous, and the consumer's experience with them, from the introduction of the idea through the procedure and aftercare, is controlled entirely by doctors. In fact, a typical patient experience is probably to be seen by one doctor, or a few doctors working in conjunction, either in the same practice, hospital, or referral system. Their practice is guided only by the regulatory mechanism discussed.¹⁸² Practice guidelines may mandate disclosure of all the options available to a patient, but there is little enforcement of them, and the myriad possible presentations of these options still allows a physician a great deal of latitude in shaping the information given. Furthermore, in the treatment setting, a patient typically has placed a great deal of trust in the doctor's professional opinion.

This situation gives the physician a great deal of power to manipulate the information a patient receives, and thus their choices, with regard to medical procedures. While there are some incentives for physicians to do their best in patient care—the tort of medical malpractice, professional and personal ethics, and the oversight of institutions and professional organizations—there are just as many strong incentives for physicians to act in their own self-interest when recommending the use of a medical procedure.

First and foremost are the motives of profit and career advancement. Fame and fortune inure to the doctors who are on the cutting edge of biomedical technology; see the name recognition Dr. Ian Wilmut, the researcher who first cloned a sheep, now enjoys.¹⁸³ And the incentive to put money before patient care extends

¹⁸¹The previous assertions are based upon the author's observations.

¹⁸²See *supra* Part II.A.

¹⁸³See, e.g., "A Clone in Sheep's Clothing", at <http://www.sciam.com/explorations/030397clone/030397beards.html> (last

to more mundane procedures as well. Allegations that surgeons perform unnecessary surgical procedures, such as hysterectomies, caesarian sections, and cardiac bypasses, instead of managing health conditions through other medical means because surgeries are more profitable are not uncommon.¹⁸⁴ Physician self-regulation is particularly ineffective at preventing this kind of misconduct by doctors because colleagues are loath to question one another's professional judgment. Also, doctors who work together, and who are thus in the best position to question the judgment calls of their partners in practice, may have developed a culture which elevates profit over patient care in this manner.

Furthermore, where there existed several possible options for treatment of a condition, a procedure may cure or improve the condition even though it is not the best treatment option.¹⁸⁵ This makes it very difficult for a patient to learn that his treatment has been mismanaged by the doctor. The only way to discover such an insidious form of malpractice is to compare the statistics for the whole of a doctor's practice. If the rates of a doctor's use of invasive, expensive, and/or complicated procedures are higher than average, malpractice may be indicated. However, this is only one possible interpretation of such facts; there may be other rational explanations for why a particular doctor performs more of these procedures than others. And the opportunity to conduct further investigations into a suspect doctor's diagnoses is practically non-existent. Doctor/patient confidentiality and the lack of enforcement power in physician self-regulation makes it unlikely that there will ever be any remedial action. Individual patients may seek a remedy via a medical malpractice lawsuit, but again, the likelihood of a successful suit is low. This is because a patient may not

visited May 16, 2002).

¹⁸⁴See generally "Needless Surgery", at <http://www.quackwatch.com/04ConsumerEducation/crhsurgery.html> (last visited May 16, 2002).

¹⁸⁵See, e.g., *Id.*; "New Book Exposes Problem of Unnecessary OB-GYN Procedures," at <http://www.bradleylewis.com/healthnews.htm> (last visited May 16, 2002); "The Epidemic of Unnecessary Mastectomy: How Not to Be a Victim", <http://members.aol.com/mpwright9/cancer.html> (last visited May 16, 2002).

even be aware that her case was managed improperly, and even if she does show that another doctor has a different opinion of how her case should have been handled, a jury may find that this is simply a case of inconsistent professional judgment not worthy of a finding of malpractice.

Defining the term “procedure” for the sake of new regulations will be difficult. What things that doctors do should be considered a “procedure” with regard to the proposed regulations? While this Paper does not attempt to classify every action a doctor might perform as a “medical procedure” or not for the sake of new regulations, there are a few key characteristics which should be considered when defining the term. First, any medical treatment on a person which requires surgery or other intrusive measures on the body should be subject to the new regulations. Second, any treatment which is likely to significantly impact a patient’s health status, either in the short- or long-term, should be considered a procedure. Third, any treatment which might have significant short- or long-term effects on the patient’s lifestyle or major life activities should be subject to the new regulations. For example, a non-surgical vasectomy would be a “procedure” because it affects the major life activity of reproduction. Not covered under such regulations would be such low-risk, non-invasive, routine medical procedures as the use of diagnostic ultrasounds. While there may be other factors that should be included, a definition primarily based on these three characteristics would bring most of the medical interventions of concern under the authority of the new regulations on procedures.

IV. A COMPREHENSIVE REGULATORY SCHEME FOR ART

Clearly, a comprehensive federal regulatory scheme for the regulation of ARTs is necessary. But the regulation of ARTs is merely one issue that must be addressed in the broader subject of reproduction’s intersection with the law. Therefore, the following plan has two goals: first, the regulation of ARTs on the federal level, but also the formation of a standing body whose mission would be to gather information and recommend cogent policies with regard to reproductive legal issues.

First, a National Commission on Life and the Law should be created in the image of the Canadian National

Commission and the New York State Commission. Second, the FDA be given the authority to regulate all medical procedures under a structure similar to that currently used to regulate drugs and devices.

A. Guiding a Federal Policy on ART: a National Commission on Life and the Law

The first step in formulating a national policy for the regulation of ARTs is to create a National Commission on Life and the Law, similar to that used in Canada and New York State. Like the New York State Commission, its mandate would be broad: to gather information from all pertinent disciplines, to process this information, to contemplate the ramifications of their conclusions, and to issue reports stating what the Commission believes should be the policy of the United States with regard to particular issues regarding the intersection of medicine and science, human life, and the law. These recommendations would include not only proposed legislation, but also regulatory and educational measures, among others. The regulation of ARTs would be only one of many issues this Commission would address, although because of the rapidly-changing nature of the ART field, I recommend that it be one of the first problems the Commission addresses.

The Commission would be staffed by experts from multiple disciplines: lawyers, doctors, scientists, bioethicists, sociologists, philosophers, social psychologists, and statisticians, among others. Approximately ten Commissioners would sit at any one time; the disciplines represented would be fixed but Commissioners would be either reappointed or replaced by the President on a staggered schedule. Commissioners would serve a term of five years. This schedule would help to ensure that the Commission maintains political balance and is not easily swayed by partisan tides.

As in the New York State and Canadian models, the Commission would not only gather information about a particular issue of life and the law from experts and scholarly research, but also from American citizens

in general. Public opinion on such issues must be ascertained early and factored into the recommendations of the Commission for several reasons, both practical and idealistic. The average American does not hold graduate degrees as the Commission experts would; in fact, only 25% of Americans are estimated to have college degrees. The Commission would not be representative of the American public without some concerted effort to derive the opinion at large. This is not only important in the abstract; it is likely necessary for the Commission to make such efforts in order for its recommendations to have the appearance of legitimacy in the eyes of the American voters. If voting Americans do not hold the Commission in respect, it is unlikely that Congress will implement its recommendations. Indeed, the Commission will almost certainly need very favorable public opinion behind it in order to convince members of Congress that it is not too politically risky to try to legislate in an area so rife with powerful opinions and discordant beliefs.

In order to obtain this public opinion, the Commission should once more follow the Canadian and New York State examples. Like Canada, the American Commission should maintain a toll-free hotline number to gather public opinion. Telephone polls and mail-in surveys should be used toward this end as well. As in New York State, telephone interviews should be conducted, not only with people who have had intimate personal contact with the particular issue under consideration, but also with randomly selected people who have no particular personal experience with the topic. Multiple sources of information will ensure a more accurate picture of American public opinion as a whole.

The Commission should report its findings and recommendations in published form both to Congress, pertinent governmental bodies and non-governmental organizations, and the American public. Included in these findings should be a detailed explanation of the deliberations and criteria that the Commission used when making its decisions. While this should be done as quickly as possible, it is likely to take years, not months, for the Commission to consider these weighty issues and render their judgments. As time passes and the particular problems of the American Commission become evident through practice, perhaps it will be advis-

able to split the duties of the Commission into multiple, topic-oriented groups, or to increase the numbers of full Commissions serving, or the number of Commissioners.

The National Commission would be independent of other executive departments and agencies. The funds required to operate the National Commission would likely be relatively insubstantial when compared to the other items in the national budget.

B. FDA Regulation of Medical Procedures

While one is hopeful that Congress would implement the recommendations of the National Commission with all due speed, that alone would not be a sufficient solution to the problem of the need to regulate ARTs more stringently. In fact, all medical procedures are in need of closer scrutiny and should be regulated under the auspices of the FDA in a manner similar to that used for drugs and devices. Heightened scrutiny should be applied to procedures that, like ARTs, are particularly controversial.

1. Premarket Notification/Approval Scheme

Medical procedures should be regulated on a tiered system like that used for medical devices. Like medical devices, procedures would be categorized according to the amount of risk they posed to the patient, the current level of knowledge about safety and efficacy, and any other pertinent factors. “Other pertinent factors” should include larger societal issues surrounding the use of a particular procedure, as has been done with regard to the classification of medical devices (see the example of electroconvulsive therapy devices). Procedures that are relatively low risk and which have a track record of proven safety and efficacy might be considered Class I procedures. As with devices, general regulatory controls would be implemented to monitor their use. These controls would include truth in labeling and advertising rules, general and specific good practice standards for the performance of all medical procedures, training requirements for practitioners performing certain procedures, maintenance of detailed records of patients undergoing particular procedures,

and perhaps bans on certain procedures found to have no real therapeutic value (“quack” procedures).

Class II procedures would be those procedures which pose less than serious risks for patients undergoing them, but for which there is not sufficient accurate data indicating safety and effectiveness. As with Class II devices, these procedures would be subject to regulatory measures above and beyond the general regulatory controls. These measures would include the development of and adherence to mandatory performance standards for a procedure, postmarket observation of the use and outcomes of a procedure, detailed patient registries, and special guidelines and/or recommendations for the use of a procedure, among others.

Class III procedures would be those procedures which are inherently high-risk for the patient, inherently high-risk for the practitioners, have an unproven track record for safety and efficacy, and/or uses which pose significant social concerns.¹⁸⁶ Some examples of Class III procedures would be heart transplants, surgery on HIV-positive patients, surgery on HIV-positive patients, experimental procedures, and the use of ARTs. These procedures would require the approval of the FDA before they could be performed on patients, with exceptions provided for life-threatening emergency and experimental use, as seen in the drug and device regulations. Class III procedures might also be required to adhere to a variety of special, procedure-specific measures of the sort applied to Class II devices.

As with medical devices, procedures used prior to the implementation of the new regulations would be grandfathered into the new regulatory program. While they would be classified and required to adhere to all the general regulatory controls applicable to medical procedures, not even Class III procedures would have

¹⁸⁶It should be noted that including “uses which pose significant social concerns” opens the door for the classification of abortion as a Class III procedure. It might therefore be desirable to add a provision stating that certain routine, long-standing abortion procedures may not be placed in the Class III category on the ground of societal concern. This Paper offers no opinion as to the wisdom of such a provision as it is outside the scope.

to go through the preapproval process by the FDA. There would be two types of exceptions to this rule that would apply regardless of classification. First, there would be specific statutory provisions for the review of certain “procedures of concern” in use prior to the passage of the new regulations. All ARTs would be subject to this type of review.¹⁸⁷ Second, the FDA would be granted the power to decide of its own accord to require review of a particular procedure of its own accord.

Finally, under the new regulatory scheme, the FDA would allow some procedures to avoid premarket approval with a notification to the agency stating that the procedure was substantially similar to a pre-regulatory procedure. There would again be two exceptions. First, specific statutes would prohibit this for particular classes of procedures, ART procedures being among them. Second, the FDA would also have the power to require a review of the procedure at its discretion.

The premarket approval scheme for procedures would have serious drawbacks that are not a concern with regard to drugs and devices. First, doctors may develop new procedures as they work, by incrementally changing the way they perform over time. What changes would be considered “new procedures” for the sake of regulation? Second, new procedures may be developed in a manner wholly different from that of drugs and devices; in fact, many of these discoveries may happen by accident in the course of treating patients. On whom does the burden fall to sponsor a new Class III procedure for FDA approval? Individual doctors, and quite probably hospitals, do not always have the resources to perform the type of preapplication research required by the FDA for drugs and devices. Who should pay for the research necessary to assure safety and efficacy?

¹⁸⁷Until the passage of new legislation after the opinion of the National Commission on ARTs is issued, however, it is unlikely that procedures in wide usage, such as AID, AIH, IVF, and GIFT, would be banned under such a regulatory reconsideration. It would, however, allow the FDA to require certain guidelines and performance standards for these procedures, particularly with regard to the dosages of fertility drugs used, the number of embryos implanted during one treatment cycle, and other issues of direct concern to patient health.

The answers to these important questions cannot be answered without a great deal of research that does not currently exist. This research will need to be done before legislators draft and pass the statutes that would authorize the FDA to regulate procedures. As a result, this Paper can offer only tentative answers. Probably the definition of a “new procedure” would include significant alterations to old procedures and entirely new procedures. “Significant alterations” would consist of changes that add high or unknown risks for the patient and/or personnel, and/or that pose greater societal concerns. And, to deal with the special nature of the development of procedures (often in the field instead of in the lab) and the problems of funding as compared to drug and device development, the regulation of medical procedures will likely permit greater experimental use of procedures and lessen the burden of proof prior to approval of a procedure, while heightening general regulatory controls, special controls, and postapproval surveillance. Reconsideration of procedures after their use will likely be frequent.

The FDA’s new mandate to regulate medical procedures will be an extremely costly one. One can estimate only on the basis of what is currently spent to regulate food, drugs, cosmetics, and devices. The budget necessary to fund the FDA would be significantly increased by the addition of medical procedures to its regulatory duties. Perhaps novel funding sources exist; however, the most likely source will be higher federal taxes. This is unfortunate but necessary. The regulation of medical procedures is justified by the same logic that supports the current regulation of drugs and devices. Therefore, it logically follows that funding concerns alone ought not to overrule the need to improve the health care Americans enjoy in this area. If Americans are willing to pay for this level of safety with regard to drugs and devices, it seems at least likely that they would be willing to pay for safety protections with regard to medical procedures.

2. Requiring Specific Disclosures of Information to Patients

Disclosure requirements similar to those provided in the 1992 Fertility Clinic Disclosure Act should be applied to all medical procedures. Doctors should be required to provide patients with disclosure forms which provide detailed information about the procedure. These should include a very particular description of the procedure itself, possible side effects, typical national success rates, typical success rates for the doctor performing the procedure, the major alternative treatments and their relative success rates, as well as the training of the practitioner performing the procedure. For surgical patients, also included in the disclosure should be at least an estimate of the doctor's rate of reliance on surgery as opposed to medical management of the disorder in question, as compared to a national, regional, or specialty average. The length of the disclosure should be keyed to the classification of the procedure. Class I procedures probably require only a short disclosure; Class III procedures a lengthy one. Length will largely be dictated by the complexity and riskiness of a procedure; however, Class III procedures should have more rigorous disclosure requirements than do Class I and II procedures.

Doctors should be required to review the form with the patients, to give the patient adequate time in which to review the form, and to provide answers to patient questions about the information in as straightforward and clear a manner possible. Patients should then be required to sign the form prior to the procedure. Exceptions would apply for emergency procedures in which it is not practically possible to have a full patient disclosure session.

V. CONCLUSION

The use of ARTs in America today creates serious concerns not only for the health of the patients undergoing the procedures and the resulting offspring, but also innumerable legal, bioethical, psychological, and sociological quandaries as well. The problems resulting from the use of ARTs are in unique in many ways,

but are also a remarkable example of a more widespread problem: the relative lack of regulation of medical procedures. The United States should undertake to create a regulatory regime that would not only seek to solve the problems of ARTs in particular but which would also address the regulation of all medical procedures. Only when the federal government has formulated a cohesive policy with regard to ARTs and created a regulatory apparatus within the FDA to aid in enforcement of that policy will these serious concerns be significantly alleviated.